SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Furosemide Tablets BP (Vet) 40 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients

Furosemide (The recommended INN and European Pharmacopoeia title of Frusemide B.P. is Furosemide 40mg)

Other ingredients

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Tablet – Oral Tablets containing the stated amount of Furosemide. Flat faced, white circular with bevelled edges and a scored half break line, embossed F40 and plain on the reverse.

4. CLINICAL PARTICULARS

4.1. Target species

Dog and cat.

4.2 Indications for use

For the treatment of oedema, the product may be used in ascites, hydrothorax, pulmonary oedema of the mammary glands or legs, as well as oedema resulting from cardiac insufficiency, hepatic or renal dysfunction, parasitism or of a traumatic origin.

4.3 Contra-indications

Do not use in acute glomerular nephritis, in electrolyte diseases, in patients with anuria, or patients that have received excessive doses of cardiac glycosides. Because of the danger of potentiating their toxic effects do not use with aminoglycoside or cephalosporin antibiotics. Allergic reactions have been associated with use with sulphonamides.

4.4 Special warnings

The patient may increase its water intake to compensate for the diuresis. Consideration should be given to restricting water intake if the patient's condition makes such a course appropriate.

4.5 Special precautions

4.5.1 Special precautions for use in animals

Prolonged dosage may on occasions justify potassium supplementation and thus monitoring for hypokalaemia should be considered, especially if the product is used in conjunction with cardiac glycosides.

4.5.2 Special precautions to be taken by the person administering the medicinal product to animals:

Wear gloves or wash hands immediately after handling tablets. In case of accidental ingestion seek medical attention and show product label and/or pack insert to the doctor.

4.6 Adverse reactions

None Reported

4.7 Pregnancy and lactation

The safety of use in pregnancy is not well established and a careful assessment of the likely benefits and potential risks should be made. A deleterious effect on lactation is to be expected, particularly if drinking water is restricted. Furosemide passes into milk, but not to a great extent.

4.8 Interactions

Potential interactions with other drugs include ototoxicity with aminoglycosides and nephrotoxicity with cephalosporins. Use in combination with sulphonamide treatment may lead to sulphonamide allergy. There is a possibility of interaction with cardiac glycosides.

4.9 Amounts to be administered and administration route

5mg/KgBW, one or two times per day. For patients weighing less than 8Kg dosage with the 20mg tablet (which may be halved) is recommended. Avoid overdosage in weak and old patients.

4.10 Overdose

Dehydration and electrolyte depletion may occur. Monitor and correct as necessary. Dosage higher than that which is recommended, may cause

transitory deafness. Cardiovascular side effects may be observed in weak and old patients following overdose.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

ATC vet Code: QC03CA01

5.1 Pharmacodynamic properties

Furosemide is a diuretic with a rapid action. It exerts inhibiting effects on electrolyte reabsorption in the proximal and distal renal tubes and in the ascending loop of Henle. It may be effective in patients who do not respond to thiazide diuretics, including those with impaired renal function.

5.2 Pharmacokinetic particulars

Furosemide is incompletely but fairly rapidly absorbed from the gastrointestinal tract. It has a biphasic half life in the plasma with a terminal elimination phase that has been estimated to range up to about 1.5 hours. Furosemide is mainly excreted in the urine. Furosemide crosses the placental barrier and is excreted in milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize starch
Pregelatinised maize starch
Magnesium stearate.

6.2 Major Incompatibilities

Not Applicable.

6.3 Shelf Life

5 Years.

6.4 Special Precautions for Storage

Store in the original container in order to protect from light.

6.5 Nature and Contents of Immediate Packaging

Polypropylene/polyethylene containers containing 1000 tablets of 40mg. Containers are placed in an individual carton with a package leaflet where a pull-out label is not used.

6.6 Special Precautions for the Disposal of Unused Medicinal Product or Waste Materials, if any

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Millpledge Ltd
Whinleys Estate
Clarborough
Retford
Nottinghamshire
DN22 9NA

8. MARKETING AUTHORISATION NUMBER

Vm 04409/4000

9. DATE OF FIRST AUTHORISATION

10 September 1998

10. DATE OF REVISION OF THE TEXT

April 2021

Approved: 22/04/21

D Austin